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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,650	02/11/2004	Rafail Zubok	532/2x4 (F-280 Cont III)	3387
27538	7590	06/24/2004	EXAMINER	
KAPLAN & GILMAN , L.L.P. 900 ROUTE 9 NORTH WOODBRIDGE, NJ 07095			MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,650	ZUBOK ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 February 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-17 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date, _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/11/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Shelokov

(USPN 6,039,763). Referring to claim 1, Shelokov discloses an apparatus for replacing a portion of an intervertebral disc in a spinal column (fig.7; col.1, lines 4-7) comprising a first member (1) having a first vertebral contact surface (2) for engagement with an endplate of a first vertebral bone in the spinal column, and having a first articulation surface (3) that is defined at least by a concave arc (arc along 3 extending between 4 and 5 in fig.1b) having a radius of curvature A about a first axis substantially perpendicular to an anterior-posterior plane of the spinal column, and by a convex arc (arc along 3 seen in fig.1a) having a radius of curvature B about a first axis substantially perpendicular to a lateral plane of the spinal column, and a second member (10) having a second vertebral contact surface (11) for engagement with an endplate of a second vertebral bone in the spinal column, and having a second articulation surface (12) that is defined at least by a convex arc (arc of 12 seen in fig.2b) having a radius of curvature C about a second axis substantially perpendicular to the anterior-posterior plane of the spinal column, and by a concave arc (arc of 12 seen in fig.2a) having a radius of curvature D about a second axis

substantially perpendicular to the lateral plane of the spinal column, wherein: an intervertebral disc space is defined substantially between the first and second endplates of the first and second vertebral bones (space occupied by 78 in fig.7), and the radii of curvature of the first (3) and second (12) articulation surfaces are sized such that the first and second articulation surfaces engage one another (fig.3a-4b) when the first and second members are disposed in the intervertebral disc space (fig.7) to enable the first and second vertebral bones to articulate in at least one of flexion, extension, and lateral bending (col.4, lines 13-16).

Referring to claims 2-3, Shelokov discloses the first and second axes perpendicular to the anterior-posterior plane of the spinal column to be substantially coaxial, or lie in a plane perpendicular to the anterior-posterior plane, and the first and second axes perpendicular to the lateral plane are substantially coaxial or lie in a plane perpendicular to the lateral plane (see figures for various views).

Referring to claims 4-5, Shelokov discloses the first (3) and second (12) articulation surfaces sized and shaped to define at least one of a first center of rotation (23) for at least one of flexion and extension located outside the intervertebral disc space (see fig.3a, 3b), and a second center of rotation for lateral bending that is located outside the intervertebral disc space (fig.4a, 4b the center of rotation of the concave arc of the top element and the convex arc of the bottom element, will be below the disc space), wherein the two are located in opposite directions.

Referring to claims 6-10, Shelokov discloses the first (3) and second (12) articulation surfaces sized to engage one another and enable them to axially rotate relative to one another through a range of angles plus/minus 3 degrees from rest (col.5, lines 47-53) and displace away from one another on axial rotations outside the range of angles, and also having point-to-point

contact during flexion, extension, lateral bending, and/or rotation (col.4, lines 13-16; see fig.3a-4b and 7).

Referring to claims 11-12, Shelokov discloses concave radius A to be greater than convex radius C and concave radius D to be greater than convex radius B (col.3, lines 66-67; col.5, lines 61-63; col.8, lines 39-42; see figures).

Claims 1-8 and 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree et al. (US 2004/0024462 A1). Referring to claim 1, Ferree discloses an apparatus for replacing a portion of an intervertebral disc in a spinal column [0002] comprising a first member (top member in fig.3a-3b and 4a-4e) having a first vertebral contact surface (top surface) for engagement with an endplate of a first vertebral bone in the spinal column, and having a first articulation surface (bottom surface) that is defined at least by a concave arc (fig.3b, 4a) having a radius of curvature A about a first axis substantially perpendicular to an anterior-posterior plane of the spinal column, and by a convex arc (fig.3a, 4d, 4e) having a radius of curvature B about a first axis substantially perpendicular to a lateral plane of the spinal column, and a second member (bottom member in fig.3a-3b and 4a-4e) having a second vertebral contact surface (bottom surface) for engagement with an endplate of a second vertebral bone in the spinal column, and having a second articulation surface (top surface) that is defined at least by a convex arc (fig.3b, 4a) having a radius of curvature C about a second axis substantially perpendicular to the anterior-posterior plane of the spinal column, and by a concave arc (fig.3a, 4d, 4e) having a radius of curvature D about a second axis substantially perpendicular to the lateral plane of the spinal column, wherein: an intervertebral disc space is defined substantially between the first and

second endplates of the first and second vertebral bones, and the radii of curvature of the first and second articulation surfaces are sized such that the first and second articulation surfaces engage one another (see figures) when the first and second members are disposed in the intervertebral disc space to enable the first and second vertebral bones to articulate in at least one of flexion, extension, and lateral bending [0007, 0024].

Referring to claims 2-3, Ferree discloses the first and second axes perpendicular to the anterior-posterior plane of the spinal column to be substantially coaxial, or lie in a plane perpendicular to the anterior-posterior plane, and the first and second axes perpendicular to the lateral plane are substantially coaxial or lie in a plane perpendicular to the lateral plane (see figures for various views).

Referring to claims 4-5, Ferree discloses the first and second articulation surfaces sized and shaped to define at least one of a first center of rotation for at least one of flexion and extension located outside the intervertebral disc space (for instance, fig.3a, the center of rotation will be located above the disc space), and a second center of rotation for lateral bending that is located outside the intervertebral disc space (and for instance in fig.3b, the center of rotation will be located below the disc space), wherein the two are located in opposite directions.

Referring to claims 6-8 and 10, Ferree discloses the first and second articulation surfaces sized to engage one another and enable them to axially rotate relative to one another (limited rotation, [0007]), and displace away from one another on at axial rotations outside the range of angles, and also having point-to-point contact during flexion, extension, lateral bending, and/or rotation (see figures).

Referring to claims 11-12, Ferree discloses and has shown in the figures, various radii of curvatures for the articulation surfaces, and has disclosed articulation in all directions [0007,0024], therefore, the concave surfaces must inherently be greater in size than the convex surfaces, in order to allow the articulation movements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shelokov (USPN 6,039,763). Shelokov discloses an apparatus for replacing an intervertebral disc substantially as claimed. Shelokov discloses articulation surfaces (3, 12) having different radii of curvature (col.3, lines 66-67; col.5, lines 61-63; col.8, lines 39-42; see figures), the concave arc surfaces being greater than the convex arc surfaces, however is silent to mention specific dimensions for such radii of curvature of the arcs. It would have been an obvious matter of design choice to have the dimensions claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree et al. (US 2004/0024462 A1). Ferree discloses an apparatus for replacing an intervertebral disc substantially as claimed. Ferree discloses elements having articulation surfaces adapted to engage one another and allow a limited amount of rotation (see figures and 0007, 0024). Ferree

is silent to mention however, the degree of rotation allowed. The amount of rotation is dependent on the dimension of the surfaces. It would have been an obvious matter of design choice to choose dimensions allowing a specific amount of rotation, plus or minus 3 degrees, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shelokov (USPN 6,039,763) or Ferree et al. (US 2004/0024462 A1) in view of Gordon (USPN 6,228,118 B1). Both Shelokov and Ferree separately disclose an apparatus for replacing an intervertebral disc substantially as claimed. Shelokov and Ferree disclose first and second elements, which articulate relative to one another (see above). Shelokov and Ferree do not disclose however, the elements having flanges with through holes. Gordon teaches in the same field of intervertebral replacements, an apparatus having first (10) and second (12) articulating elements, the elements having flanges (16) with holes (22), in order to provide a means for securely attaching to the vertebrae (col.2, lines 17-28, 35-37; col.3, lines 10-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Shelokov and Ferree's intervertebral replacement apparatus, with Gordon's teaching of having flanges with holes on intervertebral replacements, in order to provide means to securely attach the replacements to the vertebrae.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



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PRIMARY EXAMINER